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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,714	03/05/2002	Isabelle Mansuy	64481/JPW/AJM/MML	7463

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Cooper & Dunham, LLP
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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/091,714	Applicant(s) MANSUY ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-10,21-23,25-27,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8-10,21-23,25-27,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed February 15, 2006 has been entered. Claims 1, 4, 5, 8, 9, 21, 25, 26, 29, and 30 have been amended. Claims 3, 7, 11-20, 24, 28, and 31-34 have been canceled.

The remarks filed October 7, 2005 (hereinafter referred to as "the response") are considered herein.

Accordingly, Claims 1, 2, 4-6, 8-10, 21-23, 25-27, 29, and 30 remain pending in the instant application and are examined herein.

The objection to the oath/declaration is withdrawn in view of the newly submitted declaration filed October 7, 2005.

The objection to Claims 1-10 for encompassing subject matter that goes beyond the elected invention is withdrawn in view of the amendment to Claim 1 and further in view of the cancellation of Claims 3 and 7.

The rejection of Claims 21-30 under 35 U.S.C. 101 is withdrawn in view of the amendment to Claim 21 to recite the term "nonhuman." However, the claims are newly rejected under 35 U.S.C. 112, first paragraph, due to the amendment adding the term "nonhuman."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 21-23, 25-27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment to the claims introduces new matter.

The claims are now directed to “a nonhuman composition of matter.” However, the as-filed specification does not contemplate “a nonhuman composition of matter” as broadly as now claimed. The as-filed specification only contemplates “a nonhuman mammal.” As support for the amendment to Claim 21, Applicants point to the specification at page 17, lines 20-28 and page 12, lines 1-10. However, neither of the cited sections refer to a nonhuman composition of matter as now claimed. Only a “nonhuman mammal” is contemplated. This does not provide adequate support for “a nonhuman composition of matter” as broadly as now claimed.

Thus, the amended claims include new matter.

Enablement

Claims 1, 2, 4-6, 8-10, 21-23, 25-27, 29 and 30 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the Office Action of May 4, 2005, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 8, paragraph 2 of the response, Applicants assert that the claims have been amended to recite both the specific protein encoded by the second heterologous nucleic acid as well as a phenotype of the claimed transgenic mammals. The claims have been amended to recite that the second heterologous

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nucleic acid encodes a calcineurin inhibitor protein and that “the mammal exhibits enhanced calcineurin inhibitor protein expression on induction of the transcriptional activator.” However, other than the enhanced expression of the calcineurin inhibitor protein, the claimed mammals include those that exhibit a wild-type phenotype. Although the specification discloses mice that exhibit enhanced learning and memory as measured in behavioral tests, the claims cover a great variety of mammals, including mice that do not have this phenotype. Furthermore, the specification does not teach how to use a mammal that exhibits enhanced expression of a calcineurin inhibitor protein as now claimed.

At page 8, paragraph 3 of the response, Applicants assert that the present invention provides a transgenic nonhuman mammal in which the expression of a calcineurin inhibitor is spatially and temporally regulated by the addition of doxycycline. Applicants further assert that the transient expression of a calcineurin inhibitor in a mouse results in enhanced learning and memory as measured in behavioral tests, as well as increased long-term potentiation, as measured in hippocampal neurons. However, for reasons of record, the phenotype of a transgenic animal is unpredictable, and the claims cover mammals other than mice that do not have this phenotype, as well as mice that do not exhibit this phenotype. As noted in the rejection of record, the phenotypic consequences of transgene expression is influenced dramatically by genetic background. The claims continue to cover transgenic mammals having no phenotypic alteration, or having any phenotype whatsoever, as long as the mammal exhibits enhanced calcineurin protein expression. The phenotypic consequences of the enhanced calcineurin protein expression may be anything at all. However, it is the role of the specification to teach a useful phenotype, such that one of skill in the art would know how to use the claimed transgenic mammal. As noted in the rejection of record, absent a useful phenotype, the skilled artisan would not know how to use the claimed mammals. Furthermore, the specification does not teach how to use a transgenic mouse that exhibits enhanced learning and memory.

Thus, the rejection is maintained, for reasons of record.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-23, 25-27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-23, 25-27, 29 and 30 are indefinite in their recitation of "wherein the nonhuman composition of matter exhibits enhanced calcineurin inhibitor protein expression on induction of the transcriptional activator" because it is unclear how a composition of matter can express a protein. There is no requirement that the composition of matter comprises the machinery necessary for protein expression. The claims read on nucleic acids in an aqueous solution, but such a solution cannot express a protein. Furthermore, a transcriptional activator cannot induce transcription under such conditions, because the transcriptional machinery is not present.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday from 10:00 AM to 8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

A handwritten signature in black ink that reads "Anne-Marie Falk". The signature is written in a cursive, flowing style.

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER